death, immediately to inform the Commission, unless the manufacturer (including an importer), distributor or retailer has actual knowledge that the Commission has been adequately informed of such failure to comply, defect, or risk. This provision indicates that a broad spectrum of safety related information should be reported under section 15(b) of the CPSA.

(c) Sections 15 (c) and (d) of the CPSA, (15 U.S.C. 2064(c) and (d)), empower the Commission to order a manufacturer (including an importer), distributor, or retailer of a consumer product distributed in commerce that presents a substantial product hazard to give various forms of notice to the public of the defect or the failure to comply and/or to order the subject firm to elect either to repair, to replace, or to refund the purchase price of such product. However, information which should be reported under section 15(b) of the CPSA does not automatically indicate the presence of a substantial product hazard, because what must be reported under section 15(b) are failures to comply with consumer product safety rules or voluntary standards upon which the Commission has relied under section 9, defects that could create a substantial product hazard, and products which create an unreasonable risk of serious injury or death. (See §1115.12.)

(d) The provisions of this part 1115 deal with all consumer products (including imports) subject to regulation under the Consumer Product Safety Act, as amended (15 U.S.C. 2051–2081) (CPSA), and the Refrigerator Safety Act (15 U.S.C. 1211–1214) (RSA). In addition, the Commission has found that risks of injury to the public from consumer products subject to regulation under the Flammable Fabrics Act (15 U.S.C. 1191–1204) (FFA), the Federal Hazardous Substances Act (15 U.S.C. 1261–1274) (FHSA), and the Poison Prevention Packaging Act of 1970 (15 U.S.C. 1471–1476) (PPPA) cannot be eliminated or reduced to a sufficient extent in a timely fashion under those acts. Therefore, pursuant to section 30(d) of the CPSA (15 U.S.C. 2079(d)), manufacturers (including importers), distributors, and retailers of consumer products which are subject to regulation under provisions of the FFA, FHSA, and PPPA must comply with the reporting requirements of section 15(b).

[43 FR 34998, Aug. 7, 1978, as amended at 57 FR 34227, Aug. 4, 1992]

§1115.3 Definitions.

In addition to the definitions given in section 3 of the CPSA (15 U.S.C. 2052), the following definitions apply:

(a) *Adequately informed* under section 15(b) of the CPSA means that the Commission staff has received the information requested under §§1115.12 and/or 1115.13 of this part insofar as it is reasonably available and applicable or that the staff has informed the subject firm that the staff is adequately informed.

(b) *Commission meeting* means the joint deliberations of at least a majority of the Commission where such deliberations determine or result in the conduct or disposition of official Commission business. This term is synonymous with "Commission meeting" as defined in the Commission's regulation issued under the Government in the Sunshine Act, 16 CFR part 1012.

(c) *Noncompliance* means the failure of a consumer product to comply with an applicable consumer product safety rule or with a voluntary consumer product safety standard upon which the Commission has relied under section 9 of the CPSA.

(d) A *person* means a corporation, company, association, firm, partnership, society, joint stock company, or individual.

(e) *Staff* means the staff of the Consumer Product Safety Commission unless otherwise stated.

(f) *Subject firm* means any manufacturer (including an importer), distributor, or retailer of a consumer product.

[43 FR 34998, Aug. 7, 1978, as amended at 57 FR 34227, Aug. 4, 1992]

§1115.4 Defect.

Section 15(b)(2) of the CPSA requires every manufacturer (including an importer), distributor, and retailer of a consumer product who obtains information which reasonably supports the conclusion that the product contains a

defect which could create a substantial product hazard to inform the Commission of such defect. Thus, whether the information available reasonably suggests a defect is the first determination which a subject firm must make in deciding whether it has obtained information which must be reported to the Commission. In determining whether it has obtained information which reasonably supports the conclusion that its consumer product contains a defect, a subject firm may be guided by the criteria the Commission and staff use in determining whether a defect exists. At a minimum, defect includes the dictionary or commonly accepted meaning of the word. Thus, a defect is a fault, flaw, or irregularity that causes weakness, failure, or inadequacy in form or function. A defect, for example, may be the result of a manufacturing or production error; that is, the consumer product as manufactured is not in the form intended by, or fails to perform in accordance with, its design. In addition, the design of and the materials used in a consumer product may also result in a defect. Thus, a product may contain a defect even if the product is manufactured exactly in accordance with its design and specifications, if the design presents a risk of injury to the public. A design defect may also be present if the risk of injury occurs as a result of the operation or use of the product or the failure of the product to operate as intended. A defect can also occur in a product's contents, construction, finish, packaging, warnings, and/or instructions. With respect to instructions, a consumer product may contain a defect if the instructions for assembly or use could allow the product, otherwise safely designed and manufactured, to present a risk of injury. To assist subject firms in understanding the concept of defect as used in the CPSA, the following examples are offered:

(a) An electric appliance presents a shock hazard because, through a manufacturing error, its casing can be electrically charged by full-line voltage. This product contains a defect as a result of manufacturing or production error.

(b) Shoes labeled and marketed for long-distance running are so designed that they might cause or contribute to the causing of muscle or tendon injury if used for long-distance running. The shoes are defective due to the labeling and marketing.

(c) A kite made of electrically conductive material presents a risk of electrocution if it is long enough to become entangled in power lines and be within reach from the ground. The electrically conductive material contributes both to the beauty of the kite and the hazard it presents. The kite contains a design defect.

(d) A power tool is not accompanied by adequate instructions and safety warnings. Reasonably foreseeable consumer use or misuse, based in part on the lack of adequate instructions and safety warnings, could result in injury. Although there are no reports of injury, the product contains a defect because of the inadequate warnings and instructions.

(e) An exhaust fan for home garages is advertised as activating when carbon monoxide fumes reach a dangerous level but does not exhaust when fumes have reached the dangerous level. Although the cause of the failure to exhaust is not known, the exhaust fan is defective because users rely on the fan to remove the fumes and the fan does not do so.

However, not all products which present a risk of injury are defective. For example, a knife has a sharp blade and is capable of seriously injuring someone. This very sharpness, however, is necessary if the knife is to function adequately. The knife does not contain a defect insofar as the sharpness of its blade is concerned, despite its potential for causing injury, because the risk of injury is outweighed by the usefulness of the product which is made possible by the same aspect which presents the risk of injury. In determining whether the risk of injury associated with a product is the type of risk which will render the product defective, the Commission and staff will consider, as appropriate: The utility of the product involved; the nature of the risk of injury which the product presents; the necessity for the product; the population exposed to the product and its risk of injury; the obviousness of such risk; the adequacy of

warnings and instructions to mitigate such risk; the role of consumer misuse of the product and the foreseeability of such misuse; the Commission's own experience and expertise; the case law interpreting Federal and State public health and safety statutes; the case law in the area of products liability; and other factors relevant to the determination. If the information available to a subject firm does not reasonably support the conclusion that a defect exists, the subject firm need not report. However, if the information does reasonably support the conclusion that a defect exists, the subject firm must then consider whether that defect could create a substantial product hazard. (See §1115.12(f) for factors to be assessed in determining whether a substantial product hazard could exist.) If the subject firm determines that the defect could create a substantial product hazard, the subject firm must report to the Commission. Most defects could present a substantial product hazard if the public is exposed to significant numbers of defective products or if the possible injury is serious or is likely to occur. Since the extent of public exposure and/or the likelihood or seriousness of injury are ordinarily not known at the time a defect first manifests itself, subject firms are urged to report if in doubt as to whether a defect could present a substantial product hazard. On a case-by-case basis the Commission and the staff will determine whether a defect within the meaning of section 15 of the CPSA does, in fact, exist and whether that defect presents a substantial product hazard. Since a consumer product may be defective even if it is designed, manufactured, and marketed exactly as intended by a subject firm, subject firms should report if in doubt as to whether a defect exists. Defect, as discussed in this section and as used by the Commission and staff, pertains only to interpreting and enforcing the Consumer Product Safety Act. The criteria and discussion in this section are not intended to apply to any other area of the law.

[43 FR 34998, Aug. 7, 1978, as amended at 71 FR 42030, July 25, 2006]

§1115.5 Reporting of failures to comply with a voluntary consumer product safety standard relied upon by the Commission under section 9 of the CPSA.

(a) *General provision.* Under the CPSA, the Commission may rely on voluntary standards in lieu of developing mandatory ones. In recognition of the role of voluntary standards under the CPSA, section 15(b)(1) requires reports if a product fails to comply with a voluntary standard "upon which the Commission has relied under section 9" of the CPSA. The Commission has relied upon a voluntary consumer product safety standard under section 9 of the CPSA if, since August 13, 1981 it has terminated a rulemaking proceeding or withdrawn an existing consumer product safety rule because it explicitly determined that an existing voluntary standard, or portion(s) thereof, is likely to result in an adequate reduction of the risk of injury and it is likely there will be substantial compliance with that voluntary standard. (See appendix to this part 1115 for a list of such voluntary standards.) This provision applies only when the Commission relies upon a voluntary standard in a rulemaking proceeding under section 9 of the CPSA. In evaluating whether or not to rely upon an existing voluntary standard, the Commission shall adhere to all the procedural safeguards currently required under the provisions of the CPSA, including publication in the FEDERAL REGISTER of the Commission's intent to rely upon a voluntary standard in order to provide the public with a fair opportunity to comment upon such proposed action.

(b) *Reporting requirement.* A firm must report under this section if it has distributed in commerce, subsequent to the effective date of the Consumer Product Safety Improvement Act of 1990 (November 16, 1990), a product that does not conform to a voluntary standard or portion(s) of a voluntary standard relied upon by the Commission since August 13, 1981. If the Commission relied upon only a portion(s) of a voluntary standard, a firm must report under this section only nonconformance with the portion(s) of the voluntary standard relied upon by the